NAFDAC REGULATED PRODUCTS AND LICENCES - 1

"They're putting cement dust into
cattle feed to make the cows heavier:
the FDA[1] knows all about it."
--Dick Dale--

In Nigeria, the term "regulated product" refers to processed foods, beverages, and medicines for human or animal use, cosmetics, medical devices, detergents, packaged/bottled water and chemicals.

The term counterfeit, in this regard, refers to a fraudulent imitation of a product, which is intended to deceive and mislead the ultimate consumer. The World Health Organization (WHO) defines a counterfeit drug as "medicine or medicinal product, which is deliberately and fraudulently mislabeled with respect to identity and/or source".

In Nigeria, there has been a high incidence of preventable deaths caused by counterfeit or fake drugs and substandard packaged food. This is the menace that **NAFDAC**, which is the acronym for **National Agency for Foods, Drugs Administration and Control**, was established by law to curb. NAFDAC is authorized to register products of the aforementioned description in Nigeria. It carries out inspection of imported goods in various ports; it also monitors companies that manufacture drugs, cosmetics and packaged food products domestically. These activities are carried out to ensure that such products are safe for human consumption and are produced using safe facilities and procedures.

To register your product (produced, packaged or imported) with NAFDAC, below are some requirements and conditions you need to meet, to get approval and the required certificate(s) of compliance.

[1] FDA = the U.S. Food & Drug Administration

1. REGISTRATION OF DRUGS AND RELATED PRODUCTS MANUFACTURED IN NIGERIA

A. GENERAL

1. These guidelines are for the interest of the general public and in particular pharmaceutical, herbal and cosmetics industries in Nigeria.
2. It is necessary to emphasize that, no drug and related products should be manufactured, imported, exported, advertised, sold or distributed in Nigeria unless it has been registered in accordance with the provisions of ACT CAP F33 LFN 2004 (formerly decree 19 of 1993) and the accompanying guidelines.
3. A manufacturer who intends to register a drug or related product in Nigeria should first have the factory inspected by the Establishment Inspection Directorate of NAFDAC and be assigned a Certificate of Recognition as a manufacturer before an application to register the product can be made.

B. APPLICATIONS/MANUFACTURER

(a) Purchase and fill the prescribed application form. A separate application form shall be submitted for each drug product. In this context, a drug product means a separate drug formulation. However the application for registration of one dosage form with different strengths shall be made on separate application forms.

(b) A written application for product registration shall be made to the Director (Registration and Regulatory Affairs), stating the name of the manufacturer, the generic name of product, brand name (where applicable), product strength, and indications.

1. Product found to be of doubtful, little or no therapeutic value shall not be considered for registration.

2. An applicant shall not be allowed to register a formulation in more than one brand name even where different dosages of the active ingredient(s) are used.

3. All dosage forms of a particular brand name must contain the same active ingredient(s) or at least the major active ingredient(s) e.g.
   A cream - Betamethasone 10mg
   A soap - Betamethasone 20mg

C. DOCUMENTATION

Documents required for submission for product registration as applicable shall be:

1. Evidence of pre-production inspection/ Certificate of Recognition issued by NAFDAC.

2. Current Certificate of Registration/ Retention Premises, issued by the Pharmacists' Council of Nigeria (Drugs only).

3. Current annual License to Practice as a Pharmacist issued by the Pharmacists' Council of Nigeria to the superintendent Pharmacist. (Drugs only).

4. Evidence of PMG-MAN membership (Drugs only).

5. Two copies of Product Dossiers made out in accordance with the Agency's format (Drugs only).

6. Evidence of Approval for brand name from Federal Ministry of Commerce.

7. Certificate of Incorporation of the company issued by the Corporate Affairs Commission (except for drugs).

8. Comprehensive Certificate of analysis of the batch of the product for registration from the manufacturer stating name and signature of the analyst.

9. Evidence of Membership of the State's Traditional Medicines Board (Herbal Medicines).

10. Technical Document (Herbal Medicines).

D. PRODUCT

1. Three vetting samples shall be submitted upon satisfactory Pre-Registration inspection.

2. No combination drug product shall be registered unless there is proven evidence that such a product has clinical advantage over the single drug available for the same indication(s).

E. LABELLING

1. Labeling shall be informative, clear and accurate.

2. Minimum requirements on the package label in accordance with the drug labeling regulations shall be:

   a) Name of medicine (brand name) where applicable and generic name.
   b) Name and full location address of the manufacturer.
   c) Provision for NAFDAC Registration Number on product label.
   d) Batch No., Manufacturing date and Expiry date.

e) Dosage form & strength.
f) Indications, frequency, route, conditions of administration.
g) Dosage regimen on the package (OTC drugs only if there is no accompanying leaflet insert.
h) Leaflet insert, if prescription product and hospital packs with Pharmacokinetic and Pharmacodynamics information.
i) Net content of product.
j) Quantitative listing of all the active ingredients per unit dose.
k) Adequate warnings where necessary.

3. Minimum labeling requirements for herbal, nutraceuticals[2] and cosmetics:
   a) Name of medicine-brand name (where applicable) and generic/botanical name.
   b) Name and full location address of the manufacturer or distributor or vendor, etc.
   c) Provision for NAFDAC Registration Number/listing on product label.
   d) Batch No., Manufacturing date and Expiry date.
   e) Dosage form & strength.
   f) Indications, frequency, route, conditions of administration. (where applicable).
   g) Dosage regimen on the package (where applicable).
   h) Leaflet insert (where applicable).
   i) Net content of product.
   j) Quantitative listing of all the active ingredients per unit dose.
   k) Adequate warnings (where necessary).
   l) Where conspicuous in character, written directly under the brand name e.g.: VENTOLIN TABLETS “SALBUTAMOL”.
   m) Any drug product whose name or package label bears close resemblance to an already registered product or is likely to be mistaken for such registered product, shall not be considered for registration.

4. Any drug product, which is labeled in a foreign language, shall NOT be considered for registration unless an English translation is included on the label and package insert (where applicable).
5. The time line for product registration from submission of samples up to issuance of registration number is hundred (100) workdays. However, this depends on satisfactory compliance by the applicant.
6. A successful application attracts a Certificate of Registration with a validity period of five (5) years.

[2] Nutraceuticals = a broad umbrella term used to describe any product derived from food sources with extra health benefits in addition to the basic nutritional value found in foods.

F. TARRIFF

All payments to the Agency should be in Bank Draft payable to National Agency for Food and Drug Administration and Control (NAFDAC):

(i) Drug: - The sum of seventy thousand naira (N70,000.00) only plus 5% VAT per product, covering processing, analysis and license.

(ii) Traditional Medicines - Categorized as follows:
  (a) Small Scale Industry: Ten thousand naira (N10,000.00) only plus 5% VAT.
  (b) Medium Scale Industry: Twenty thousand naira (N20,000.00) only plus 5% VAT.
  (c) Large Scale Industry: - Forty thousand naira (N40,000.00) only plus 5% VAT.

(iii) Phytomedicines[3]: Seventy thousand naira (N70,000.00) only plus 5% VAT.

(iv) Nutraceuticals: Seventy thousand naira (N70,000.00) only plus 5% VAT.

(v) Cosmetics: - Fifty thousand naira (N50,000.00) only plus 5% VAT.

G. NOTE

1 Registration of a product does not automatically confer Advertising Permit. A separate approval by the Agency shall be required if the product is to be advertised.

2 NAFDAC may withdraw the certificate of Registration in the event that the product is advertised without express approval from the Agency.

3 NAFDAC reserves the right to revoke, suspend or vary the certificate during its validity period.

4 Filling an application form or paying for an application form does not confer registration status.

5 Failure to respond promptly within 30 workdays to queries or enquiries raised by NAFDAC on the application, will automatically lead to suspension of further processing of the application.

6 Registration time line after submission of vetting samples is one hundred (100) work days.

All correspondence in respect of Drug registration should be addressed to:

The Director,
Registration & Regulatory Affairs
NAFDAC Central Laboratory Complex Oshodi, Lagos.
NAFDAC website: www.nafdac.gov.ng
e-mail address: registration@nafdac.gov.ng
Telephone number: +234-1-4772452, 01-4748627

[3] Phytomedicines = medicines from plant materials in their natural form.

2. REGISTRATION OF IMPORTED DRUG PRODUCTS IN NIGERIA NAFDAC/RR/002/00

A. GENERAL

1. These guidelines are for the interest of the general public and in particular, pharmaceutical industries in Nigeria.

2. It is necessary to emphasize that, no drug shall be manufactured, imported, exported, advertised, sold or distributed in Nigeria unless it has been registered in accordance with the provisions of ACT CAP F33 LFN 2004 (formerly decree 19 of 1993) and the accompanying guidelines.

B. APPLICATIONS/MANUFACTURER

1. (a) An application for registration of a drug product shall be made by the manufacturer.

   (b) In case of a manufacturer outside Nigeria such shall be represented in Nigeria by a duly registered pharmaceutical company.

   (c) An applicant for a manufacturer outside Nigeria must file evidence of **Power of Attorney** from the manufacturer which authorizes him to speak for his principal on all matters relating to the latter's specialties. The original Power of Attorney must be notarized in the country of origin by a Notary Public and submitted to NAFDAC, or a Contract Manufacturing Agreement (where applicable). This should be notarized in the country of origin by a Notary Public and submitted to NAFDAC.

   NOTE: The representative in Nigeria, whether a corporate body or an individual with the power of attorney, will be held responsible for ensuring that the competent authority in the country is informed of any serious hazard newly associated with a product imported under the provisions of the Act or of any criminal abuse of the certificate in particular to the importation of falsely labeled, spurious, counterfeited or sub-standard medicinal products.

2. (a) The applicant shall submit to the office of the Director (Registration and Regulatory Affairs), a written application, stating name of the manufacturer, generic name, brand name (where applicable), strength, indications and obtain the prescribed application form which must be properly filled with all required information.

   (b) A separate application form shall be submitted for each drug product. In this context, a drug product means a separate drug formulation. However the application for registration of one dosage form with different strengths shall be made on a separate application form.

C. DOCUMENTATION

1. The manufacturer, in the case of imported drug products (from India and China only), must submit evidence that they are licensed to manufacture drugs for sale in the country of origin **(Manufacturer's Certificate).** The competent Health Authority in the country of manufacture must issue such evidence.
2. There must be evidence that the drug product is manufactured according to Good Manufacturing Practice (GMP).
3. There must be evidence by the competent Health Authority that the sale of the product does not constitute a contravention of the drug laws of that country, i.e. **Certificate of Pharmaceutical Product (COPP) that conforms to WHO format.** The Nigerian Mission in that country shall authenticate The documents in respect of C1-3. In countries where no Nigerian Embassy or High Commission exists, any other Embassy or High Commission of any Commonwealth or West African country can authenticate.
4. The applicant shall submit two (2) dossiers made out in accordance with the Agency's format.
5. Evidence of Trade Mark Approval for brand name from Federal Ministry of Commerce in Nigeria should be submitted.
6. Copy of current Annual Licence to Practice as a Pharmacist for the Superintendent Pharmacist issued by Pharmacists Council of Nigeria should be submitted.
7. Copy of Current Certificate of Registration Retention of Premises issued by Pharmacists Council of Nigeria.
8. Comprehensive Certificate of analysis of the batch of product submitted for registration processing shall be submitted.

D. PRODUCT

1. A drug product shall not be manufactured in Nigeria, unless the factory is inspected and Certificate of Recognition is issued by NAFDAC.
2. In the case of an imported new drug substance, there must be evidence that limited local clinical trials have been undertaken, and that such product is registered in the country of origin and also, in at least 2 or more developed countries.
3. No combination drug product shall be registered or considered for registration unless there is proven evidence that such a product has clinical advantage over the single drug available for the same indication(s).
4. The application should indicate the class or type of registration required - whether a prescription only product or Over the Counter.
5. Product found to be of doubtful, little or no therapeutic value shall not be considered for registration.
6. An applicant shall not be allowed to register a formulation in more than one brand name even where different doses of the active ingredient(s) are used.
7. All dosage forms of a particular brand name must contain the same active ingredient(s) or at least the major active ingredient(s) e.g. A Cream - Betamethasone 10mg, A Soap - Betamethasone 20mg.

E. LABELLING

1. Labelling shall be informative, clear and accurate.

2. Minimum requirements on the package label in accordance with the drug labeling regulations should be:
   (a) Name of medicine (brand name) where applicable and generic name.
   (b) Name and full location address of the manufacturer.
   (c) Provision for NAFDAC Registration Number on product label.
   (d) Batch No., Manufacturing date and Expiry date.
   (e) Dosage form & strength.
   (f) Indications, frequency, route, conditions of administration.
   (g) Dosage regimen on the package (OTC drugs only if there is no accompanying leaflet insert.
   (h) Leaflet insert, if prescription product and hospital packs.
   (i) Net content of product.
   (j) Quantitative listing of all the active ingredients per unit dose.
   (k) Adequate warnings where necessary.

3. Where a brand name is used, there MUST be the generic name which should be conspicuous in character, written directly under the brand name e.g., VENTOLIN TABLETS "SALBUTAMOL"

4. Any drug product whose name or package label bears close resemblance to an already registered product or is likely to be mistaken for such registered product, shall not be considered for registration.

5. Any drug product that is labeled in a foreign language shall NOT be considered for registration unless an English translation is included on the label and package insert (where applicable).

F. TARRIF

All payments to the Agency are payable by bank draft to the National Agency for Food and Drug Administration and Control.

1.	Over The Counter (OTC) Medicines	One million naira (=N=1,000,000.00) plus 5% VAT per product
2.	Prescription Only Medicines (POM)	Two hundred and fifty thousand Naira (N250,000.00) plus 5% VAT per product
3.	Orphan Drugs	Eighty thousand Naira (N80, 000.00) plus 5% VAT per product.
4.	The Drug form labeled "FORM D - REG/001"	N500.00 (five hundred naira)

G. TIMELINE

The timeline for product registration from submission of samples up to issuance of registration number is a hundred (100) workdays. However, this is subject to satisfactory compliance by the applicant.

H. NOTE

(1) Registration of a product does not automatically confer Advertising permission. A separate approval by the Agency shall be required if the product is to be advertised.

(2) NAFDAC may withdraw the certificate of Registration in the event that the product is advertised without express approval from the Agency.

(3) NAFDAC reserves the right to revoke, suspend or vary the certificate during its validity period.

(4) Filling an application form or paying for an application form does not confer registration status.

(5) Failure to respond promptly (within 30 working days) to queries or enquiries raised on the application, will automatically lead to suspension of further processing of the application.

(6). A successful application attracts a Certificate of Registration with a validity period of five (5) years.

All correspondences in respect of Drug registration should be addressed to:

The Director,
Registration & Regulatory Affairs
NAFDAC Central Laboratory Complex
Oshodi, Lagos.
NAFDAC website: http://www.nafdac.gov.ng
E-mail address: registration@nafdac.gov.ng

3. NATIONAL AGENCY FOR FOOD & DRUG ADMINISTRATION & CONTROL

PORTS INSPECTION DIRECTORATE

GUIDELINES FOR CLEARANCE OF IMPORTED DRUGS (HUMAN AND VETERINARY) AND RELATED PRODUCTS IN NIGERIA
NAFDAC/PID/001/00

A. GENERAL

1. These guidelines are for the interest of the general public and in particular importers of registered pharmaceutical and related products into Nigeria.

2. Please be informed that all importation of Drugs and related products must be by pharmaceutical companies that registered the products.

3. These guidelines are also intended for importers of registered medical devices except that pharmacist and retention of premises licenses issued by Pharmacist Council of Nigeria are exempt documents for clearance from the port of entry.

4. It is necessary to emphasize that, no drugs and related products should be manufactured, imported, exported, advertised, sold or distributed in Nigeria unless it has been registered in accordance with the provisions of Act Cap F33 LFN 2004 (formerly decree 19 of 1993) and the accompanying guidelines.

5. Please note that the importation of unregistered drug product(s) or registered drug products by persons or companies other than those that registered the products should be regarded as a violation.

6. Vaccines and biologicals must be accompanied by functional cold chain monitoring devices at the ports of entry and must be maintained according to stipulated conditions at company's warehouse.

B. APPLICATION

1 The application should be by the company that registered the product(s) with NAFDAC or company granted "Letter of Authorization" by the party that registered the products. It should be noted that such importations are restricted to only registered sources(s) as stated on the Product Registration Certificate(s).

2 The applicant should make available to Ports Inspections Directorate, NAFDAC the following pre-shipment information before any drug consignment arrives Nigeria from any part of the world:

Name of the drug product(s)
Manufacturer's Name and Address
Quantity being imported
Various pack sizes, strength of the drug(s) and the dosage form
Batch number(s), Manufacture and Expiry dates
Conveying Vessel and expected date of arrival

C. DOCUMENTATION

1. To ensure that the quality, safety and efficacy of the drugs imported from India, China and Egypt, comply, NAFDAC appointed analysts to inspect and analyze products in these countries before shipment into Nigeria as follows:

1	INDIA	QCS Consultants
2	CHINA	NHU LABS LTD
3	EGYPT	Inspection & Testing Group (ITG)

a. All drugs and related product(s) from the listed countries should be issued 'Clean **Report of Inspection and Analysis'** before shipment into Nigeria.

b. The Current Pharmacist's Annual License to Practice as a Pharmaceutical Chemist issued by Pharmacist Council of Nigeria.

c. The Current Premises/Retention Certificate issued by Pharmacist Council of Nigeria.

d. The following shipping documents should be submitted for obtaining "First Stamp":

   i. Single Goods Declaration (SGD) Form,
   ii. Commercial Invoice
   iii. Risk Assessment Report
   iv. Form M
   v. Bill of Lading/Airway Bill
   vi. Packing List

e. Photocopy of Narcotics Permit to import and Permit to clear (where applicable).

f. Evidence of valid product registration certificate with NAFDAC.

g. Certificate of Analysis (Original) issued by the manufacturer.

2. Originals of all the above documents should be sighted

D. TARRIFF

1. All payments to the Agency must be in bank draft in favour of National Agency for Food and Drug Administration & Control and the following fees, as appropriate should apply per product covering inspection and analysis:

2. Inspection fee per consignment of an ethical drug (prescription) is Twenty thousand naira (N20, 000.00) plus 5% VAT,
3. Laboratory Analysis fee per product of an ethical drug (prescription) is Fifty thousand naira (N50, 000.00) plus 5% VAT,
4. Inspection fee per consignment of an OTC drug (non-prescription) is One hundred thousand naira (N100, 000.00) plus 5% VAT
5. Laboratory Analysis fee per product of an OTC drug (non-prescription) is Two hundred thousand naira (N200, 000.00) plus 5% VAT,
6. Inspection fee per consignment of vaccine(s) or biological product(s) is Ten thousand naira (N10, 000.00) plus 5% VAT,
7. Laboratory Analysis fee per product of a vaccine or biological product is Forty thousand naira (N40, 000.00) plus 5% VAT,
8. Inspection fee per consignment of medical devices is Ten thousand naira (N10, 000.00) plus 5% VAT,
9. Laboratory Analysis fee per product of medical devices is Twenty-five thousand naira (N25, 000.00) plus 5% VAT,
10. Inspection fee per consignment of cosmetic products is Twenty thousand naira (N20, 000.00) plus 5% VAT,
11. Laboratory Analysis fee per product of a cosmetic product is Fifty thousand naira (N50, 000.00) plus 5% VAT,
12. A consignment is defined as packaged goods in not more than 20ft container.

E. PRESENTATION OF DOCUMENTS FOR PRE-RELEASE FIRST STAMP

1. In addition to the earlier listed documents, the following are required before a pre-release first stamp is endorsed on the original SGD Form.

    i. A letter of undertaking stating that the product(s) will be forfeited if found unsatisfactory
    ii. The address of warehouse where product will be stored.

2. Evidence of payment for the imported consignment.

F. PHYSICAL EXAMINATION

1. Physical examination of the consignment shall be conducted by NAFDAC with other relevant Government Agencies at the Port of Entry.
2. Samples of the imported product(s) should be drawn during physical examination by NAFDAC and forwarded to the relevant NAFDAC laboratory for analysis and radiation test (where applicable) within 24 hours of drawing such samples.
3. One-third (1/3) of the sample drawn should be given to the superintendent pharmacist of the company as retention sample.

G. RELEASE OF CONSIGNMENT FROM THE PORT OF ENTRY

1. The drugs should be released to the importer's warehouse pending satisfactory Laboratory analysis, which should be within a period of ten workdays from the date of sample collection.
2. The drug(s) can only be marketed after satisfactory Laboratory analysis by NAFDAC.

H. CORRESPONDENCE

All correspondence in respect of importation of Drugs and related products should be addressed to:

The Director,
Ports Inspections Directorate, NAFDAC
NAFDAC Laboratory Complex,
Yaba, Lagos.
E-mail address: portsinspections@nafdac.gov.ng

4. GUIDELINES FOR PACKAGING BULK SEMI–FINISHED DRUG PRODUCTS IN NIGERIA

A. GENERAL

1. These guidelines are for the interest of the general public and in particular pharmaceutical industries in Nigeria.

2. These guidelines are for industries that may wish to import bulk semi-finished drug products and other regulated products i.e. nutraceuticals, food supplements in drums or sacks for the purpose of packaging them in Nigeria.

3. It is necessary to emphasis that, no drug should be manufactured, imported, exported, advertised, sold or distributed in Nigeria unless it has been registered in accordance with the provisions of ACT CAP F33 LFN 2004 (formerly decree 19 of 1993 (as amended)) and the accompanying guidelines.

4. The guidelines also apply to manufacturer of an already registered imported drug product who may choose to import the semi – finished bulk product to package in Nigeria.

B. APPLICATIONS

a) An application for registration of a drug/related product should be made by the manufacturer or importer on the company's letterhead paper.

b) In the case of a drug manufacturer outside Nigeria, such should be represented in Nigeria by a duly registered pharmaceutical company. Therefore, the application should be accompanied with:
   i. Current Certificate of Registration/ Retention of Premises issued by the Pharmacists Council of Nigeria.
   ii. Current Annual Licence to Practise as a Pharmacist issued by the Pharmacists Council of Nigeria to the Superintendent Pharmacist.

c) In the case of other regulated products, companies duly registered in Nigeria could represent.

a) The applicant must also submit duly filled prescribed application form.

b) A separate application form should be submitted for each product. In this context, a product means a separate formulation. However the application for registration of one dosage form with different strengths should be made on a separate application form.

C. DOCUMENTATION

1 An applicant for a manufacturer outside Nigeria must file evidence of Power of Attorney from the manufacturer which authorizes him to speak for his principal on all matters relating to the latter's specialties. The original Power of Attorney should be signed stating name and designation of the officer and should be notarized by a notary Public in the country of origin. This shall be submitted to NAFDAC.

Or Where the applicant in Nigeria owns the trademark of the drug manufactured outside Nigeria under contract arrangement, such applicant should submit a Contract Manufacturing Agreement which:

(i) Should be notarized by a notary public in the country of manufacture.

(ii) Should be signed by both parties stating names and designations of the signatories with the names of all the products to be registered.

NOTE:

The representative or applicant in Nigeria, whether a corporate body or an individual with the power of attorney, will be held responsible for ensuring that the competent authority in the country is informed of any serious hazard newly associated with a product imported under the provisions of the ACT or of any criminal abuse of the certificate in particular to the importation of falsely labeled, spurious, counterfeited or sub-standard medicinal products.

2. (a) The manufacturer, in the case of imported drug / related products (from Asia), must show evidence that he or she is licensed to manufacture drugs for sale in the country of origin (Manufacturer's Certificate).

(b) There must be evidence by the competent Health Authority, that the sale of the product does not constitute a contravention of the drug laws of that country. i.e. Certificate of Pharmaceutical Product (COPP) that conforms to WHO format. (Drugs only)

(c) Certificate of Free Sale (For herbal, nutraceuticals and food supplements products only).

(d) Current Good Manufacturing Practice (GMP) Certificate of the manufacturing facility shall be submitted (for manufacturers from Asian countries).

The documents in respect of (a) to (d) above should be issued by the relevant health/regulatory body in the country of manufacture and authenticated by the Nigerian Mission in the country of manufacture. In countries where no Nigerian Embassy or High Commission exists, authentication by the British Embassy or High Commission of any Commonwealth or West African country shall be acceptable.

3. Applicant should submit Certificate of Registration of Brand Name with

the trademark Registry in Nigeria.(where applicable). The trademark registration should be done in the name of the trademark owner as the case may be.

4. A letter of Invitation to inspect the factory abroad. This should be written by the applicant in Nigeria and should state the full location address of the manufacturer, Name of contact person, e-mail address, current phone no. & fax no., guide map illustrating the shortest land/air route to the factory overseas.

5. Certificate of Incorporation of the importing company issued by the Corporate Affairs commission in Nigeria. (Except for drugs).

6. Upon satisfactory assessment of all the above documents, permit to import the bulk semi-finished product should be issued to the applicant after the payment of necessary fees

7. If a product is already registered with subsisting product license, a permit to import bulk semi finished product should be issued without need to re-submit documents listed in B1 – B5 above. (The manufacturer's information should remain the same as registered otherwise treat as Change of source)

D. INSPECTION

Upon satisfactory evaluation of documents, Establishment Inspection Directorate should assess the GMP of the plant intended for packaging.

E. PRODUCTS

Upon satisfactory inspection of the packaging line, three (3) samples of the product intended for registration should be submitted with the following documents:

i. A letter on the company's letterhead stating the company's intention i.e. 'Submission of product samples for registration".

ii. Copy of permit to import bulk semi – finished product.

iii. Copy of receipt of payment for inspection.

iv. Copy of product dossier with the product's Certificate of Analysis for the batch submitted. (For drugs only).

v. Certificate of analysis (For other regulated products).

F. LABELLING

1. Product label should be clear, informative and accurate.
2. The minimum requirements on the package label are as follows:
    a. Name of medicine (brand name) where applicable and

generic name.

b. i. Name and full plant address of the manufacturer, vendor, packer or distributor etc.

iii. Name and address of manufacturer shall read manufactured by .....; Packaged by ..... (for drugs only).

c. Provision for NAFDAC Registration / Listing Number on product label.

d. Batch Number, Manufacturing date and Expiry date.

e. Dosage form & strength. (as appropriate).

f. Indications, frequency, route, conditions of administration (may be on the primary and secondary package label of OTC drugs but not on POM drugs).

g. Dosage regimen on the package (OTC labels only).

h. Package leaflet insert (as appropriate).

i. Quantitative listing of all the active ingredients per unit dose.

j. Adequate warnings (where necessary).

k. Net content.

l. A disclaimer stating "These claims have not been evaluated by NAFDAC" should be prominently written on the labels and literature insert of the product. (For herbal products only).

3. Where a brand name is used, the generic name should be conspicuous in character, VENTOLIN "SALBUTAMOL"

4. Any drug / related product whose name, package or label bears close resemblance to an already registered product or is likely to be mistaken for such registered product, shall not be considered for registration.

5. Any drug / related product which is labeled in a foreign language shall NOT be considered for registration unless an English translation is included on the label and package insert

6. Information on indication carried on package labels and package insert of imported drug products shall not differ from that in other countries, and in particular the country of origin of the product.

G. TARIFF

All payments to the Agency should be in bank draft in favour of the National Agency for Food and Drug Administration and Control.

1. Application Form =N=500:00.

2. Prescription-only drug product =N=175, 000:00 + 5% VAT

3. Over-the-Counter drug product =N=700, 000:00 + 5% VAT
4. Nutraceuticals / food supplement product =N=525, 000:00 + 5% VAT
5. Herbal drug product =N=262, 500:00 + 5% VAT
6. Herbal drug product from ECOWAS. =N=105, 000:00 + 5% VAT
7. Product line as GMP inspection fee =N=10, 000: 00 + 5% VAT

NOTE

(i) Registration of a product does not automatically confer Advertising permit. A separate approval by the Agency should be required for product advertisement.

(ii) NAFDAC may withdraw the certificate of Registration in the event that the product is advertised without express approval from Agency.

(iii) NAFDAC reserves the right to revoke, suspend or vary the certificate during its validity period.

(iv) Filling an application form or paying for registration processing does not confer registration status.

(v) Failure to respond promptly in writing to queries raised by NAFDAC on the application will automatically lead to suspension of further processing of the application.

(vi) A successful application attracts a Certificate of Registration with a validity period of five (5) years or listing for two (2) years.

All correspondence in respect of registration should be addressed to:

THE DIRECTOR (R&R) NATIONAL AGENCY FOR FOOD & DRUG ADMINISTRATION AND CONTROL,
CENTRAL LABORATORY COMPLEX, OSHODI, LAGOS.
NAFDAC website: www.nafdac.gov.ng
E-mail address: registration@nafdac.gov.ng